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APPLICATION NO.				. 03-41 US	6822
10/788,592	02/27/2004		Stig Pedersen-Bjergaard	05-11-05	
23693	7590	11/15/2007	•	EXAMINER MUI, CHRISTINE T	
Varian Inc.					
Legal Departm	ient Voi: D. 102		ART UNIT	PAPER NUMBER	
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Palo Alto, CA 94304				1797	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)					
	10/788,592	PEDERSEN-BJERGAARD ET AL.					
Office Action Summary	Examiner	Art Unit					
	Christine T. Mui	1797					
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply							
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DOWN THE MAILING DOWN THE MAILING DOWN THE MAILING DOWN THE MAILING THE METERS AND THE MAILING THE METERS AND	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim vill apply and will expire SIX (6) MONTHS from , cause the application to become ABANDONE	N. sely filed the mailing date of this communication. D (35 U.S.C. § 133).					
Status		•					
1)⊠ Responsive to communication(s) filed on <u>07 S</u>	eptember 2007.						
	action is non-final.						
·—	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is						
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.							
Disposition of Claims							
4) ⊠ Claim(s) <u>1,2,4-6,9-20,22-24 and 46-51</u> is/are p 4a) Of the above claim(s) is/are withdray 5) □ Claim(s) is/are allowed. 6) ⊠ Claim(s) <u>1-2, 4-6, 9-20, 22-24 46 and 48-50</u> is/ 7) ⊠ Claim(s) <u>47 and 51</u> is/are objected to. 8) □ Claim(s) are subject to restriction and/o	wn from consideration.  /are rejected.						
Application Papers							
9) The specification is objected to by the Examine 10) The drawing(s) filed on is/are: a) acc Applicant may not request that any objection to the Replacement drawing sheet(s) including the correct 11) The oath or declaration is objected to by the Example 11.	epted or b) objected to by the I drawing(s) be held in abeyance. See tion is required if the drawing(s) is obj	e 37 CFR 1.85(a). jected to. See 37 CFR 1.121(d).					
Priority under 35 U.S.C. § 119							
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No.</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>							
Attachment(s)  1) Notice of References Cited (PTO-892)  2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date	4) Interview Summary Paper No(s)/Mail Do 5) Notice of Informal F 6) Other:	ate					

#### **DETAILED ACTION**

#### Election/Restrictions

Claims 25-45 are withdrawn from further consideration pursuant to 37 CFR
 1.142(b) as being drawn to a nonelected methods, there being no allowable generic or linking claim. Election was made without traverse in the reply filed on 08 May 2007.

## Response to Arguments

Applicant's arguments filed 13 September 2007, with respect to the rejection(s) of claim(s) 1-24 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejections for claims 1-2, 9-10, 13-24, 46 and 50 are made in view of WO 02/0088672 to Varian, Inc. and further in view of USP 5,507,949 to Ho (herein referred "Ho"). Furthermore, new ground(s) of rejections for claims 4-5 Varian, Inc. and Ho, and further in view of USP 3,959,173 to Li (herein referred "Li"); claim 6 is rejected under Varian, Inc. and Ho, and further in view of USP 5,603,953 to Herbig et al (herein referred "Herbig"); claim 12 is rejected under Varian, Inc. and Ho, and further in view of Jonsson et al (herein referred "Jonsson"); claims 16 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Varian, Inc. and Ho, and further in view of USP 4,990,334 to Admassu (herein referred "Admassu"); and claims 48-49 is rejected under Varian, Inc. and Ho, and further in view of USP 5,160,627 to Cussler et al. (herein referred "Cussler").

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## Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-2, 9-10, 13-20, 22-24, 46 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 02/0088672 (herein referred "Varian, Inc.", and further in view of USP 5,507,949 to Ho (herein referred "Ho").

Regarding claim 1, the reference Varian, Inc. discloses a device for performing clean-up and enrichment of analytes of interest. A donor sample comprising of an analyte of interest is inserted into a tubular hollow porous fiber into a well, where the hollow fiber comprises of a liquid extraction membrane. The hollow fiber enclosing an internal cavity is separated from the donor sample by the extraction membrane and a static acceptor liquid is placed in the internal cavity. Enriching a cleaning up of the analyte of interest by extracting the analyte of interest from the donor is through the extraction membrane into the acceptor liquid in the internal cavity. The analyte of interest is transferred and the acceptor liquid from the internal cavity is transferred to the analysis device (see page 1, line 29 - page 2, line 5). Varian, Inc. does not disclose the membrane comprising of a support comprising of a fatty acid ester, a vegetable oil or silicon oil. Ho discloses an immobilized liquid membrane for the selective extraction where the membrane comprises of a polymeric liquid supported or immobilized within a microporous support, which may be hydrophobic. It is known in the art that a media for removing halogenated hydrocarbons from aqueous streams may be in contact with a microporous polyolefin film impregnated with silicone oil, vegetable oil and animal fats and waxes. In an example where an immobilized liquid membrane is prepared in a cell, silicone oil was used as the liquid membrane (see abstract, column 2, lines 13-21,

column 14, lines 11-12). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use silicon oil as the liquid membrane to enhance separation and isolation of the analyte of interest.

Regarding claim 2, the references Varian, Inc. and Ho discloses the claimed invention. Varian, Inc. discloses the membrane used in the invention can be produced in many forms such as a hollow fiber (see page 6, lines 9-10).

Regarding claim 9, the reference Varian, Inc. and Ho disclose the claimed invention. Varian, Inc. discloses the microporous semi-permeable membrane permite selective filtration according to the size of the micropores. The molecular weight cutoff of membrane allows passage of small molecules such as drugs while precluding passage of large molecules such as proteins. The porous electrically charged or ion-exchanged membranes have a pore wall with fixed positive or negative charges. The passage of ionic molecules across the membrane is governed by pore size and membrane charge. The analytes of interest pass through the membrane into the acceptor solution, leaving interferences in the donor solution (see page 6, lines 12-22).

Regarding claim 10, the references Varian, Inc. and Ho disclose the claimed invention. Varian, Inc. discloses in the supported liquid membranes the pH of the donor solution is adjusted below the pKa value of the acid, the ionization of the carboxylic acid is suppressed and the nonionic form to be extracted is allow to form into the immobilized liquid membrane. Polymeric membranes are also formed by the polymerization of monomers in the pores of the support material (see page 7, lines 8-11, page 8, lines 30-31).

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Regarding claims 13-15, the references Varian, Inc. and Ho disclose the claimed invention. Varian, Inc. discloses the polymeric membrane from the polymerization of monomers in the pores of the support materials which can be a polymer such as polyalkylene glycols, polyvinylpyrrolidones, polyesters, polyurethanes and functionalized polyolefins. The fibers in the well plates may also be modified by several permutations and combinations of parameters to incorporate selectivity features, which would permit the isolation of a single analyte from a complex mixture. The fibers can be made from different polymeric materials such as polypropylene, polysulfone, polycarbonate or polyether sulfone (see page 8, line 30-page 9, line 1, page 10, lines 13-18).

Regarding claim 16-17, the reference Varian, Inc. and Ho disclose the claimed invention. Varian, Inc. does not disclose the liquid membrane is stable for at least 30, 60 or 90 days and where the hollow fiber is able to extract at least one analyte after being stored for at least 30, 60 or 90 days. Ho discloses the stable supported liquid membrane can handle and stored for months at room temperature air due to the practically nonvolatile nature of PPG the microporous polypropylene membrane wet with polypropylene glycol and the same wetting procedure can be used for hollow fiber membrane (see column 11, lines 1-13). It is interpreted by the examiner that since the supported liquid membrane and the hollow fiber are made by the same wetting technique, the storage of the membrane is the same time frame. Furthermore, it is interpreted by the examiner that the storage time of months can be up to 90 days or even more. It would have been obvious to one having ordinary skill in the art at the time the invention was made to preserve the hollow fiber liquid membrane for months at

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a time so that one can make many hollow fiber membranes at one and store the remaining membranes for future uses while not worrying about the integrity of the membrane separation capabilities.

Regarding claim 18, the reference Varian, Inc. and Ho disclose the claimed invention. Varian, Inc. discloses in a two-phase extraction system an aqueous fee solution is on the shell side of the fiber and organic solvent acceptor solution is on the lumen side with the same solvent forming the supported membrane (see page 12, lines 1-3).

Regarding claim 19, the reference Varian, Inc. and Ho disclose the claimed invention. Varian, Inc. discloses in a simple supported liquid membrane hollow fiber devices can be employed in the well plate and an autosample vial formats in a state mode can furnish a high degree of sample enrichment (see page 11, lines 30-32).

Regarding claim 20, the reference Varian, Inc. discloses a device for performing clean-up and enrichment of analytes of interest. A donor sample comprising of an analyte of interest is inserted into a tubular hollow porous fiber into a well, where the hollow fiber comprises of a liquid extraction membrane. The hollow fiber encloses an internal cavity separated from the donor sample by the extraction membrane and a static acceptor liquid is placed in the internal cavity. Enriching a clean up of the analyte of interest is done by extracting the analyte of interest from the donor through the extraction membrane into the acceptor liquid in the internal cavity. The analyte of interest is transferred and the acceptor liquid is transferred from the internal cavity to the analysis device (see page 1, line 29 – page 2, line 5). Varian, Inc. does not disclose the

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membrane comprising of a support comprising of a fatty acid ester, a vegetable oil or a silicon oil. Ho discloses an immobilized liquid membrane for the selective extraction where the membrane comprises of a polymeric liquid support or immobilized within a microporous support, which may be hydrophobic. It is known in the art that a media for removing halogenated hydrocarbons from aqueous streams may be in contact with a microporous polyolefin film impregnated with silicone oil, vegetable oil and animal fats and waxes. In an example where an immobilized liquid membrane is prepared in a cell, silicone oil was used as the liquid membrane (see abstract, column 2, lines 13-21, column 14, lines 11-12). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use silicon oil as the liquid membrane to enhance separation and isolation of the analyte of interest.

Regarding claims 22-23, the references Varian, Inc. and Ho disclose the claimed invention. Varian, Inc. discloses the polymeric membrane is formed from the polymerization of monomers in the pores of the support materials which can be a polymer such as polyalkylene glycols, polyvinylpyrrolidones, polyesters, polyurethanes and functionalized polyolefins. The fibers in the well plates may also be modified by several permutations and combinations of parameters to incorporate selectivity features, which would permit the isolation of a single analyte from a complex mixture. The fibers can be made from different polymeric materials such as polypropylene, polysulfone, polycarbonate or polyether sulfone (see page 8, line 30-page 9, line 1, page 10, lines 13-18).

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Regarding claim 24, the reference Varian, Inc. and Ho disclose the claimed invention. Varian, Inc. does not disclose the liquid membrane is stable for at lease 30, 60 or 90 days. Ho discloses the stable supported liquid membrane can be handled and stored for months at room temperature air due to the practically nonvolatile nature of PPG the microporous polypropylene membrane wet with polypropylene glycol and the same wetting procedure can be used for hollow fiber membrane (see column 11, lines 1-13). It is interpreted by the examiner that the storage time of months can be up to 90 days or even more. It would have been obvious to one having ordinary skill in the art at the time the invention was made to store and preserve the liquid membrane for months at a time keep a stock of liquid membranes to one doe not need to make membranes every time separation of analytes needs to occur.

Regarding claim 46, the reference Varian, Inc. and Ho disclose the claimed invention. Varian, Inc. discloses a membrane was formed with small molecular weight organic liquids that comprised of an aryl alkyl ether containing the polar nitro functionality (see page 34. lines 23-26).

Regarding claim 50, the reference Varian, Inc. and Ho disclose the claimed invention. Varian, Inc. discloses a membrane was formed with small molecular weight organic liquids that comprised of an aryl alkyl ether containing the polar nitro functionality (see page 34. lines 23-26).

Claims 4-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Varian, Inc. and Ho as applied to claim 1 above, and further in view of USP 3,959,173 to Li (herein referred "Li").

Regarding claims 4-5, the references Varian, Inc. and Ho discloses the claimed invention except for where the fatty acid ester comprises of an acyl chain comprising from 12 to 30 carbon atoms. Li discloses a liquid membrane based off of the formulation of emulsions, where emulsion are used for the separation of dissolved components from aqueous solutions. The emulsion of the liquid membrane comprises of an oil-soluble surfactant, which can include an nonionic surfactant. The most preferred nonionic surfactant is Span 80 TM from Atlas Chemical, a fatty acid ester of anhydrosorbitol (see abstract, column 3, lines 62-66, column 4, lines 30-32). It is known in the art that Span 80 TM has an acyl chain of 18 carbons and an ester portion of 8 carbons. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the membrane be made of a fatty acid ester with an acyl chain from 12 to 30 carbon atoms so that membrane is resistant to cleavage of donor or acceptor solutions in the well and may sustain multiple uses.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Varian, Inc. and Ho as applied to claim 1 above, and further in view of USP 5,603,953 to Herbig et al (herein referred "Herbig").

Regarding claim 6, the references Varian, Inc. and Ho disclose the claimed invention except for where the vegetable oil is soya oil, olive oil or teatree oil. Herbig discloses a supported liquid membrane delivery device that releases a beneficial agent to an aqueous environment used in solvent extraction. The device in the invention included a polyvinylidenefluoride or polyalkene porous membrane with a triglyceride entrained therein. Preferred within the group are devices where the hydrophobic liquid

membrane is triolein or olive oil. In an example using the device, a supported liquid membrane was produced by filling the pores of a disk of Accurel A3 polypropylene membrane with olive oil (see abstract, column 3, line 30-33, column 12 line 66-column 13, line 2, column 15, lines 40-44). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the liquid membrane be of a vegetable oil so that beneficial agent are released when in used in the extraction of a solvent.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Varian, Inc. and Ho as applied to claim 1 above, and further in view of Jonsson et al (herein referred "Jonsson").

Regarding claim 12, the references Varian, Inc. and Ho disclose the claimed invention except for where the carrier is an organic ion selected from the list presented in the claim. Jonsson discloses membranes used in the extraction in analytical chemistry in sample preparation can be made of TOPO, DEHPA or trioctylmethylammonium in the detection of acids, metal ions or amino acids or amino acids amino phosphonic acid, respectively (see abstract, Table 1). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use TOPO, DEHPA or trioctylmethylammonium as part of the membrane in the detection of analytes to specifically separate analytes of interest according to ones needs for experimentation.

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Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Varian, Inc. and Ho as applied to claim 1 above, and further in view of USP 4,990,334 to Admassu (herein referred "Admassu").

Regarding claim 16, the references Varian, Inc. and Ho discloses the claimed invention. Varian, Inc. does not disclose the liquid membrane is stable for at least 30, 60 or 90 days. Admassu disclose a method for treating liquid-wet polycarbonate membrane to improve separation properties where they are stored in water at ambient or elevated temperature and pressure for a period of time sufficient to provide uniform membrane composition. The membranes are preferably stored in water at ambient temperature and pressure for at least 2 hours and more preferably for at least 24 hours, even more preferably for at least 5 days, and most preferably for 10 days (see abstract, column 4, lines 54-61). It would have been obvious to one having ordinary skill in the art at the time the invention was made to store the liquid membranes for at least 30, 60 or 90 days to allow complete formation of the liquid membrane promoting better separation and to store the membranes for future use in different experimentation.

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Varian, Inc. and Ho as applied to claim 20 above, and further in view of USP 4,900,334 to Admassu (herein referred "Admassu").

Regarding claim 24, the references Varian, Inc. and Ho discloses the claimed invention. Varian, Inc. does not disclose the liquid membrane is stable for at least 30, 60 or 90 days. Admassu disclose a method for treating liquid-wet polycarbonate membrane to improve separation properties where they are stored in water at ambient

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or elevated temperature and pressure for a period of time sufficient to provide uniform membrane composition. The membranes are preferably stored in water at ambient temperature and pressure for at least 2 hours and more preferably for at least 24 hours, even more preferably for at least 5 days, and most preferably for 10 days (see abstract, column 4, lines 54-61). It would have been obvious to one having ordinary skill in the art at the time the invention was made to store the liquid membranes for at least 30, 60 or 90 days to allow complete formation of the liquid membrane promoting better separation and to store the membranes for future use in different experimentation.

Claim 48 is rejected under 35 U.S.C. 103(a) as being unpatentable over Varian, Inc. and Ho as applied to claim 2 above, and further in view of USP 5,160,627 to Cussler et al. (herein referred "Cussler").

Regarding claim 48, the reference Varian, Inc. and Ho disclose the claimed invention except for where the liquid membrane supported on a hollow fiber is stored in a closed container prior to use. Cussler discloses a process for modifying the properties of a hydrophobic microporous member where the pore-filled microporous hollow fiber members are used in a broad range of chromatographic separations applications such as liquid-liquid extractions and the pore-filled hollow fibers constitute stabilized, immobilized liquid membranes having a utility generally where the membranes are needed. A module of the hydrophobic microporous member comprises of a housing and plurality of hollow fibers (see column 8, lines 22-31, claim 3). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide a housing for the membranes to be stored in before use to preserve

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the separation integrity of the membrane and the prevent contamination form the environment and human touch before use.

Claim 49 is rejected under 35 U.S.C. 103(a) as being unpatentable over Varian, Inc. and Ho as applied to claim 20 above, and further in view of USP 5,160,627 to Cussler et al. (herein referred "Cussler").

Regarding claim 49, the reference Varian, Inc. and Ho discloses the claimed invention except for where the liquid membrane supported on a hollow fiber is stored in a closed container prior to use. Cussler discloses a process for modifying the properties of a hydrophobic microporous member where the pore-filled microporous hollow fiber members are used in a broad range of chromatographic separations applications such as liquid-liquid extractions and the pore-filled hollow fibers constitute stabilized, immobilized liquid membranes having a utility generally where the membranes are needed. A module of the hydrophobic microporous member comprises of a housing and plurality of hollow fibers (see column 8, lines 22-31, claim 3). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide a housing for the membranes to be stored in before use to preserve the separation integrity of the membrane and the prevent contamination form the environment and human touch before use.

## Allowable Subject Matter

Claims 47 and 51 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

A hollow fiber liquid membrane on a porous polymeric substrate with a preservative in the use of liquid extraction is not found in the prior art.

### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine T. Mui whose telephone number is (571) 270-3243. The examiner can normally be reached on Monday-Friday 8-5; Alternate Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Walter Griffin can be reached on (571) 272-1447. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CTM

WALTER D. GRIFFIN SUPERVISORY PATENT EXAMINER